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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,160	02/06/2002	Dennis Klinman	4239-61997	9731

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/068,160

**Applicant(s)**

KLINMAN ET AL.

**Examiner**

Dave T. Nguyen

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8, 12-15, 19-22 and 60-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 12-15, 19-22, and 60-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/04 &amp; 10/04</u> . | 6) <input type="checkbox"/> Other: _____  |

It has come to the examiner's attention that the IDS dated October 15, 2004 has not been considered by the examiner at the time the final Office action dated 1/12/2005 was prepared and mailed. As the result, the finality of the office action dated 1/12/2005 is vacated by the examiner. The following final office action is a corrective action as the result of the availability of the IDS (dated 10/15/2004) together with the references cited therein.

In addition, the references cited in the Supplemental information disclosure statement stamped by the USPTO on April 22, 2004 were not in file. Thus the IDS has not been considered and initialed. The copies of the references should be provided to the examiner in a next communication. The IDS stamped by the USPTO on March 10, 2004 has been considered and initialed by the examiner.

Claims 8, 12-15, 19-22, and 60-66 have been amended; Claims 16-18 have been canceled; and Claim 67 has been added by the amendment dated 10/13/04.

Claims 8, 12-15, 19-22, and 60-67 are pending.

While the claim amendment and applicant's response have obviated all outstanding objections and rejection other than the remaining ODP rejection as set forth in the non-final office action dated January 29, 2004, following are new grounds of the rejection as the result of the availability of a prior art cited by the IDS dated October 15, 2004.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Acknowledgment is made of applicant's claim for priority based on PCT/US00/09329 application filed on April 12, 2000, which in turns claim priority to US provisional Application No. 60/128,898, filed on April 12, 1999. However, it appears that neither the PCT application nor the provisional application has written support for the generic structure as claimed in presently pending claim 8. More specifically, no written support was provided in either of the applications so as to lead a person skill in the art to have reasonably believed that applicant was in possession of the claimed invention as broadly claimed presently at the time the invention was made. It is noted, however, while one species (SEQ ID NO: 1) was disclosed in the PCT application, for example, such species is not the same as claiming broadly the genus of oligos with the generic formula as set forth in claim 8. As such, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e), and therefore, priority for the claimed invention as claimed in claim 8 can only be granted to the filing date of the instant application, February 6, 2002.

Claim 8, 13-15, 19-22, 60-65, and 67 are rejected under 35 USC 102(a) or 102(e) as being anticipated by Hartmann *et al.* (WO 01/22990, wherein the ground of rejection does not appear to have priority to its provisional application 60/156,147).

The main thrust of the claimed invention is the make and use of an isolated stabilized oligo of between 18 and 30 nucleotide in length, comprising a sequence represented by the formula as set forth in base claim 8, wherein a combination of a poly G, the sequence Pu1pY2CpGPu3pY4, and a padridromic structure comprising sequence X1X2X3Pu1Py2 and Uu3Py4X4X5X6 are presented in the oligo.

Hartmann *et al* teaches the same on SEQ ID NO: 36 (page 4), which is: ggGGTC**GACGT CG ACGTC**GAGggggG, which is a stabilized oligo, wherein each lower case letter represents phosphorotioate linkage and each upper case letter indicates phosphodiester linkage. SEQ ID NO: 36 does appear to have a combination of a poly G, the sequence Pu1pY2CpGPu3pY4, and a padridromic structure comprising sequence X1X2X3Pu1Py2 and Pu3Py4X4X5X6 are presented in the oligo. SEQ ID NO: 36 does have at least 5 G based nucleotides at the 5' end. Also, Hartmann *et al.* teaches that it is well-recognized in the prior art with regard to immunostimulatory properties of poly-G nucleic acids, which can be defined as 5'X1X2GGGx3X4 3', wherein X1, X2, X3, and X4 are nucleotides (see pages 23 and 24). In fact, Hartmann *et al* teaches that oligos (referred as ISNAs) can include any combination of at least two types of ISNAs, including CpG nucleic acids, T-rich nucleic acids, and poly-G nucleic acids (page 25). A phosphodiester central region is taught on page 25. Stabilized oligos such as the make and use of a phosphorothioate linkage is also disclosed on

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page 6 bridging page 7. Targeting means such as lipid components, viruses, cationic lipids, ligand can be used to bind ionically or covalently to the oligos, see page 35.

Thus, Hartmann *et al* anticipates the claimed invention.

Hartmann is not the prior art against the sequences of SEQ ID NOS: 1, 2, 31, 73, 12-15, since those sequences were disclosed in the provisional application 60/128,898 and its '839 PCT application. With respect to SEQ ID NO: 17, which is disclosed only in the instantly filed application, the prior art of record does not teach, suggest or provide a motivation to arrive specifically at SEQ ID NO: 17.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 12-15, 19-22, and 60-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 09/958,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims embrace SEQ ID NO: 1 of this as-filed application or SEQ ID NO: 12 of the copending application and a pharmaceutical composition comprising the sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Ram Shukla*, may be reached at **571-272-0735**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

**For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.**

Dave Nguyen  
Primary Examiner



**DAVE TRONG NGUYEN  
PRIMARY EXAMINER**